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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/524,454	03/10/2000	Kristian Berg	697.013US1	5804

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EXAMINER	
EWOLDT, GERALD R	

ART UNIT	PAPER NUMBER
1644	

NOTIFICATION DATE	DELIVERY MODE
03/25/2011	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

uspto@slwip.com
request@slwip.com

Office Action Summary	Application No.	Applicant(s)	
	09/524,454	BERG ET AL.	
	Examiner	Art Unit	
	GERALD EWOLDT	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01 February 2011*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *2,4,8,9,28-30,41 and 43-50* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *2,4,8,9,28-30,41 and 43-50* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *2/01/11*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. A request for continued examination (RCE) under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed 2/01/11 in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's amendment, remarks, and IDS filed 2/01/11 have been entered.

2. Claims 2, 4, 8, 9, 28-30, 41, and newly added Claims 43-50 are pending and being acted being acted upon.

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 2, 4, 8, 9, 28-30, 41, and newly added Claims 43-50 stand/are rejected under 35 U.S.C. 102(b) as being anticipated by WO 96/07432 (IDS).

WO 96/07432 teaches a method of presenting an antigenic molecule on the surface of a viable cancer cell (e.g., NHIK 3025m a cervical carcinoma cell line), said method comprising:

contacting said cell *in vitro* and *ex vivo* with said antigenic peptide (including a vaccine component, a molecule capable of stimulating an immune response, and a peptide, also including an antigen bound to a carrier molecule) and with a photosensitizing agent (a porphyrin, phthalocyanine, purpurin, chlorin, benzoporphyrin, naphthalocyanine, cationic dye, and tetracycline, including $TPPS_4$, $TPPS_{2a}$, and $AlPcS_{2a}$, also including a photosensitizing agent bound to a carrier molecule);

wherein said molecule and said agent are each taken up into an intracellular membrane-restricted compartment of said cell; and,

irradiating said cell with light of a wavelength effective to activate the photosensitizing agent, such that the membrane of said intracellular compartment is disrupted, releasing said

molecule into the cytosol of the cell, without killing the cell by irradiation;

wherein, said released antigenic molecule, or a part thereof of sufficient size to generate an immune response, is subsequently presented on the surface of said cell by a class I MHC molecule (see particularly the claims).

Note that the reference does not specifically state that the method results in the cell surface expression of the antigen in MHC Class I, however, the reference teaches the same steps as those of the instant claims, thus, said same steps would inherently result in the same outcome, i.e., the claimed method of the presenting an antigenic peptide on the surface of a viable cell. The reference further teaches the *in vivo* administration of and antigen and photosensitizing agent (page 6, "injection of the treated cells" and page 7, "clinical utilization"). As elaborate *ex vivo* methods of disease treatment are not routinely performed on animals such a fish or birds, the administration of the treated cells to a mammal is readily envisaged.

Applicant's arguments, filed 2/01/11 have been fully considered but they are not persuasive. Applicant argues that the reference fails to disclose administering cells to mammals or methods of using cancer cells.

Applicant's remark is addressed in the body of the rejection.

Applicant argues that new Claim 43 includes *in vitro* killing of the treated cell by a T cell.

While the claim may "include" (encompass) *in vitro* killing, it is not so limited.

Applicant argues that the reference does not use the terms "antigen" or "T cell".

Under proper conditions any protein or peptide would be an antigen. T cells are inherent to the mammal to which the treated cells are administered.

Applicant argues that inherency requires more than that a result or characteristic may occur.

If the same steps are performed employing the same reagents it is inherent that the same result or characteristic will be achieved. Absent that certainty the method of the claims would not be enabled given that much of that which is encompassed by the claimed method has not actually been done. Also note that at page 4 of the specification Applicant *admits* that they have simply further characterized the method of WO 96/07432, "We have now found that such a method [that of WO 96/07432] can advantageously be used, not only to transfer molecules in the interior of a cell, **but also to present or express them on a cell surface**". That is, Applicant *admits* that the method of WO 96/07432 results in the cell surface presentation of the internalized peptide.

Applicant argues that the claims of the reference are generic in nature.

Applicant's argument is curious in that the instant claims are also generic in nature.

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 2, 4, 8, 9, 28-30, 41, and newly added Claims 43-50 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, specifically:

A) Claims 2, 4, 8, 9, 28-30 and 41 are vague and indefinite as the conclusion step of independent Claim 2 does not result in the method of the preamble. The preamble recites a method of "presenting an antigenic peptide on the surface of a viable cancer cell" whereas the conclusion of the method is "administering the cell to a mammal". It appears that Applicant is actually trying to claim a method of treatment. If so, the preamble of the claim should so recite. Accordingly, the metes and bounds of the claim cannot be determined.

B) Claims 43-50 are vague and indefinite as it is unclear what the point of the claimed method is and what it encompasses. The specification appears to primarily teach a method for loading antigen presenting cells (APCs) with a specific antigen *ex vivo*. Said APCs could then be introduced into a subject to

induce an immune response to the peptide of interest. The relevant Examples simply show that PCI functions to get a peptide into a cell and presented on the cell surface with Example 3 (which is essentially the method of Claim 43) showing that the cell expressing the peptide of interest can then be killed by a CTL specific for that peptide. While interesting, it is unclear how this showing would relate to any actual therapy. Why would a cancer cell be removed from a patient, manipulated by PCI to present a particular peptide, and then killed by a CTL, whether *in vitro* or *in vivo*? More simply, if *in vitro* killing is the goal, bleach would be more effective. Regarding *in vivo* killing, it would appear to make no sense to reintroduce a cancer cell into a subject just to kill it.

Further regarding the method of Claim 43, while the antigen presentation appears to be induced *in vitro*, it is unclear where the CTL killing occurs. If the killing occurs *in vitro* then the claim requires the *in vitro* contacting of the cancer cells with a CTL specific for the peptide that it is presenting. Such a step/limitation is not present in the claim. Accordingly, the metes and bounds of the claim cannot be determined.

7. No claim is allowed.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dr. Gerald Ewoldt whose telephone number is (571) 272-0843. The examiner can normally be reached Monday through Thursday from 7:30 am to 5:30 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Ram Shukla, can be reached on (571) 272-0878.

9. **Please Note:** Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197.

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